CERTIFICATE OF TRANSMISSION

[X] Pursuant to 37 C.F.R. § 1.10. I hereby certify that this paper and all enclosures are being deposited with the United States Postal Service "Express Mail _____ to Addressee on the date indicated below in an envelope addressed to the Mail Stop _____, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313.

[ ] Pursuant to 37 C.F.R. § 1.6(d), I hereby certify that this paper and all enclosures are being sent via facsimile on the date indicated below to the attention of Examiner Willse, D. at Facsimile No. (703) 872-9303.

Dated: 4/5, 2005 Name of Person Certifying: Peggy Nichols
Peggy Nichols

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

David J. SCHANZLIN, et al.

Serial No.: 08/993,696

Filed: December 18, 1997

For: **RADIAL INTRASTROMAL CORNEAL INSERT AND A METHOD OF INSERTION**

Group Art Unit: 3738

Examiner: Willse, D.

DECLARATION OF THOMAS A. SILVESTRINI UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

1. Dear Sir:

2. I, Thomas A. Silvestrini, citizen of the United States of America, hereby declare that:

3. I have a Bachelor of Science degree in Chemical Engineering and a Master of Science degree in Organic Chemistry, each from the University of Minnesota. From 1990 to 2001, I was Vice-President of Research and Development of KeraVision, Inc. a medical device company. I also am a co-inventor of many of the patents and currently pending applications, including the subject application, that were previously assigned to KeraVision, Inc. The patent rights in the patents and pending applications have been assigned to Addition Technology, Inc., the assignee of the above-identified application. I

am currently Chief Technical Officer of AcuFocus, Inc., where I continue to develop products and conduct research in the development of medical devices and methods to correct vision. In view of the above, I believe that I am one of skill in the art.

4. I have read the subject application papers and the Final Office Action issued September, 1, 2004, including the references cited by the Patent Office against the pending claims. It is my understanding that the U.S. Patent Examiner rejected claims 86-93 under 35 U.S.C. § 103(a) as allegedly unpatentable over Herrick, U.S. Patent No. 4,781,187 ("the '187 Patent"). The Examiner acknowledged that the '187 Patent teaches employment of donor corneal tissue as the implant material but that substitution of a synthetic polymer material would have been obvious in order to provide greater control over material properties, to reduce risk of disease transmission, to ensure availability of materials, and so on, especially in the absence of any advantage or criticality in the instant disclosure of synthetic polymers over natural polymers.

5. In my opinion, the '187 Patent does not suggest employment of synthetic polymer material in corneal inserts and it would not have been an obvious straightforward substitution of synthetic for natural material. In considering a potential alternative to donor cornea tissue, one skilled in the art would reasonable have sought out material having properties closely matched to those of donor corneal material. One important consideration in this regard would have included whether or not the implant would maintain its position in the cornea after implantation, especially during movement of the eye and during blinking, otherwise known as migration.

6. A person skilled in the art would have been concerned that migration of the implants would become a problem if the implants were changed from donor corneal tissue. Implant migration can adversely affect the desired refractive correction and cause irritation. In making implants from corneal tissue it would have been expected that this material choice would minimize or eliminate the possibility of implant migration. The implants would be seen as advantageously having a similar modulus to that of the cornea

in which they are implanted and would not thus be expected to be susceptible to undesirable implant slippage or migration. On the other hand, a corneal segment made of a material having a modulus different to that of corneal tissue (such as a synthetic, polymeric segment) would have been expected to slip or migrate more readily.

7. In addition, the implants would be seen as advantageously maximizing cross-linking between the insert and the surrounding corneal material, due to the similarities in the two materials. At the priority date of the present invention it was known that in wound healing the ~~cells~~ tissue in the cornea will cross-link with ~~each other~~ itself in the formation of a scar. Cross-linking between a corneal material insert and the surrounding corneal material would not only improve wound healing, but would also have the effect of anchoring the insert material to the surrounding corneal material, improving resistance of the insert to undesirable slippage or migration. In moving away from the implant being donor corneal material, one of skill in the art would have thought that cross-linking between the insert and the surrounding corneal material would be reduced or eliminated, with a consequent reduction in immobilization of the insert within the corneal material. The person skilled in the art would have feared that, in switching to a synthetic, polymeric material for the insert, there would be no cross-linking between the insert and the surrounding corneal material, with the consequent risk of a reduction in immobilization forces acting on the insert and/or in the promotion of wound healing.

8. Peristaltic action typically tends to squeeze and move an object. The eyelid peristaltic-type action due to blinking or rubbing of the eye would thus have been expected to exacerbate the potential for slip or migration of a synthetic, polymeric segment. At the priority date of the present invention the skilled person starting with the disclosure of the use of donor tissue would thus be concerned that, in changing from a corneal tissue implant material to another material, for example a synthetic, polymeric material, there would be an undesirable reduction in implant stability and wound healing.

9. The U.S. Patent Examiner also rejected claims 88, 89, and 91-93 under 35 U.S.C. § 102(a) as allegedly anticipated by Civerchia, US Pat. No. 5,213,720 (the '720 Patent). The Examiner stated that the embodiments shown in Figures 14 and 17 can be inserted into the cornea (Figure 4; column 6, lines 20-21; column 18, lines 9-12) and thus possess a radius of curvature along a centroidal axis of at least 5.0 mm; because of their elongate form, these embodiments clearly extend in a meridional direction. Regarding claims 88 and 89, the Office argued that the particular radius of curvature would have been immediately obvious from the anatomy depicted in Figure 4. With respect to claims 91-93, the Office argued that the length of the tabs 132 being less than or equal to 2.0 mm would have been obvious from the drawing (Figure 17) and would have been obvious in order to lessen the trauma to the cornea.

10. The '720 Patent also does not teach or suggest the invention because it discloses disk-like implants, similar to contact lens. It is my opinion that the '720 Patent only discloses lenses to be placed over the pupilary zone of the eye to correct vision. (See col. 10, line 34 to 61 of the '720 Patent which describes the embodiments of Figures 14 and 17). Modification of the shape of the eye, using inserts of the subject invention, are not disclosed or suggested by the '720 Patent.

11. I further declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

3/30/05
Dated

Thomas A. Silvestrini